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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,300	10/26/2001	Erich Grotewold	22727/04066	6818
24024	7590	05/07/2003		
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			EXAMINER MEHTA, ASHWIN D	
			ART UNIT 1638	PAPER NUMBER
DATE MAILED: 05/07/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/044,300	GROTEWOLD, ERICH
	Examiner Ashwin Mehta	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 26 October 2001.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing for "Mol et al., Trends in Plant Science" (document "AR" on page 2) in the IDS submitted 15 February 2002 has been lined through, because the entry is incomplete. The date of publication, volume number, and page numbers are missing, and are not printed on the reference.

### ***Claim Objections***

2. Claims 1, 3, and 12 are objected to because of the following informalities:

In claim 1, line 1, "differed" should be --different--.

In claim 3, line 1, "promote" should be --promoter--.

In claim 12, line 3, "combinations" should be singular.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-11 and 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation "was derived" in line 3 renders the claim indefinite. It is not exactly clear what is meant by "derived." It is suggested that the recitation "from which the transgenic grass plant was derived" be deleted.

In claim 16: the recitation "corresponding non-transgenic plants" in line 2 renders the claim indefinite. It is not clear if the color of the transgenic plant is to be compared to that of a non-transgenic plant of the same species, or any grass species. It is suggested that "plants" in the recitation be changed to the singular form, and that the recitation "of the same species" be inserted in line 2 before ", comprising".

Further in claim 16: part b) of the claim also renders it indefinite, as it indicates a use of plant cells or protoplasts, without reciting a positive method step. It is suggested that the recitation in part b) be replaced with --regenerating a transgenic grass plant from said plant cell or protoplast--.

In claim 20: the claim is indefinite because it is not clear if the transgene referred to in lines 2-5 of the claim is the same as or different from the transgenic mentioned in claim 1. It is suggested that the article "a" in line 2 of claim 20 be replaced with --said--, and that the claim end after the recitation "transgene" in line 2.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11-15 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for microprojectile bombardment and Agrobacterium-mediated methods to introduce nucleic acid constructs into grass, does not reasonably provide enablement for other methods to introduce nucleic acid constructs into grass, C1/R chimeric genes, a method for making transgenic grasses by introduction of a C1 gene alone into grass cells, and combinations of stress-inducible promoters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any transgenic grass plant whose color phenotype is different from the corresponding non-transgenic grass plants, comprising introducing a nucleic acid construct into a plant cell or protoplast comprising any exogenous anthocyanin regulatory gene, operably linked to a promoter; or wherein the anthocyanin gene is the maize C1 gene, maize R gene, a combination of maize C1 and maize R genes, or a chimeric maize C1/R gene; or wherein the nucleic acid is introduced into plant cells using microprojectile bombardment, electroporation, Agrobacterium-mediated transformation, microinjection, induced uptake, aerosol beam injection, direct DNA uptake, liposomes, and combinations thereof; or a nucleic acid construct comprising an anthocyanin gene from the group consisting of C1 gene, R gene, a combination of C1 and R genes, or a chimeric C1/R gene, operably linked to a stress-inducible promoter.

The specification indicates that the invention provides for transgenic grass expressing an exogenous anthocyanin regulatory gene and exhibiting color different from that of a corresponding non-transgenic grass (page 2, lines 10-31). The specification provides prophetic

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examples in which the maize R and C1 genes are operably linked to the CMV 35 S promoter, and introduced into Kentucky bluegrass embryonic calli or perennial ryegrass by particle bombardment (page 13, line 8 to page 14, line 2). A prophetic example is also provided in which the rab28 gene promoter sequence is operably linked to a "C1/R" chimeric regulatory gene, and introduced into embryogenic calli suspension cultures of Kentucky bluegrass, Perennial ryegrass, or Tall fescue by particle bombardment (page 14, lines 5-15).

However, the specification does not teach all of the methods for grass transformation listed in the claims. While there are examples in the prior art for particle bombardment and Agrobacterium-mediated methods of grass transformation, examples are lacking in the prior art for grass transformation using any of the other methods listed in claim 17. While the specification makes references to methods of plant transformation generally (page 10, lines 1-24), it does not teach how all of these methods can be used with grass species. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine how all of the transformation methods listed in claim 17 can be used to transform all grass species. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

The specification also does not teach any "chimeric C1/R gene." The specification at page 6, lines 18-25, discusses a chimeric protein, termed "CRC," that is a translational fusion of the maize C1 protein Myb domain, the maize R protein, followed by the C1 C-terminus. However, the specification does not teach any chimeric gene referred to as "C1/R," and the specification does not teach that the designations "C1/R" and "CRC" are interchangeable.

Rather, the specification teaches that a construct comprising both the maize C1 and R genes is called "C1/R" (page 6, lines 11-14), and this is not a chimeric gene. As discussed above, page 14 of the specification provides an example in which a "C1/R" chimeric gene is supposedly used. However, this example is prophetic and does not teach what this C1/R chimeric gene actually is. One skilled in the art cannot practice the claimed invention using a "chimeric C1/R gene," as the specification does not teach what this gene is.

The specification also does not enable the production of transgenic grass with a different color phenotype by transforming the grass with a C1 gene alone. Lloyd et al. (Science, 1992, Vol. 258, pages 1773-1775) teach that transgenic plants expressing a maize C1 gene alone had no effect on the host plant (abstract; page 1773). It is not clear how one skilled in the art can cause a color change in a transgenic plant by expressing an exogenous C1 gene in it, as this gene product alone will not produce any effect.

Furtherstill, regarding claim 13: the claim limits the type of stress inducible promoter that can be present in the construct of claim 12, and indicates that the promoter may be a combinations of the listed promoters. However, the specification does not provide any guidance in how one may combine any of the promoters to form a single promoter that is still inducible. It is not at all clear how one skilled in the art is to combine any of the listed promoters to yield a functional, stress-inducible promoter. See Genentech, Inc. V. Novo Nordisk, A/S, supra. Given the breadth of the claims encompassing various method of grass transformation, chimeric C1/R genes, and expression of C1 genes alone to produce differences in color phenotype in transgenic grasses, unpredictability of the art, and lack of guidance of the specification, undue

experimentation would be required by one skilled in the art to make and use the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhalla et al. (WO 96/22015) in combination with Lloyd et al. (Science, 1992, Vol. 258, pages 1773-1775) and Applicant's admitted state of the prior art.

The claims are broadly drawn towards any transgenic grass plant whose color phenotype differs from the color phenotype of a corresponding non-transgenic grass plant of the same species, the transgenic grass plant comprising any exogenous anthocyanin gene operably linked to any promoter; or wherein the promoter is stress-inducible or chemical-inducible; or wherein the grass is a turfgrass; or wherein the anthocyanin regulatory gene is a maize C1 gene, maize R gene, a combination of a maize C and a R gene, and a chimeric maize C1/R gene; or a nucleic acid construct comprising an anthocyanin gene from the group consisting of C1 gene, R gene, a combination of C1 and R genes, or a chimeric C1/R gene, operably linked to a stress-inducible promoter; or a method for making the transgenic grass plant; or a seed of any generation of the transgenic grass plant.

Bhalla et al. teach a method to transform grass tissues, and regenerate transgenic grass therefrom, via microparticle bombardment. Bhalla et al. teach that the method can be used with any grass falling within the major subfamilies, including Bermuda grass, and to transfer genetic material to alter characteristics such as the expression of pigment genes (page 4, line 21 to page 5, line 1; page 14, line 5 to page 17, line 7; claims).

Bhalla et al. do not teach anthocyanin regulatory genes, stress-inducible or chemical-inducible promoters.

Lloyd et al. teach Arabidopsis and tobacco plants transformed with a cDNA encoding the maize R anthocyanin protein or additionally with a cDNA encoding a maize C1 anthocyanin regulatory protein, wherein the transgenic plants have augmented anthocyanin pigmentation. The cDNAs were under the control of the CaMV 35S promoter, and at least one of the R clones used had the entire untranslated leader (pages 1773-1774).

Applicant's admitted state of the prior art teaches that steroid-inducible promoters and drought-responsive promoters, such as the maize rab28 gene promoter, were known in the prior art (page 7, lines 1-18).

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to use the method of grass transformation of Bhalla et al. to introduce exogenous anthocyanin regulatory genes into grass, such as the maize C1 and R cDNAs taught by Lloyd et al. One would have been motivated to introduce the anthocyanin regulatory cDNAs into grass, given the teaching of Bhalla et al. that the transgenic grass may have altered expression of pigment genes, and the teaching of Lloyd et al. that transgenic expression of the maize C1 and R proteins resulted in altered pigmentation of the host plants. It

was also obvious that any promoter may have been operably linked to the anthocyanin regulatory cDNAs, including the maize rab28 gene promoter or a steroid-inducible promoter, which Applicant's admitted state of the prior art indicates were also available before the time of the instant invention. Any promoter in the prior art could have been used, the choice depending on one's desired end. It would also have been obvious to produce seed from the transformed plant, for the purpose of propagation.

***Contact Information***

Any inquiry concerning this communication from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

April 30, 2003



ASHWIN D. MEHTA, PH.D  
PATENT EXAMINER